

**Notice of Allowability**

Application No.

10/803,530

Examiner

Sheridan L. Swope

Applicant(s)

DARROW ET AL.

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 21, 2005.
2. ☒ The allowed claim(s) is/are 13.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>0704</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                           | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

Applicant's election of Invention II, Claims 12 and 13, and the sub-invention (A), SEQ ID NO: 2, in the response of November 21, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-15 are pending. Claims 1-11, 14, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 12 and 13 are hereby examined.

#### ***Priority***

The valid priority date for the elected invention is June 30, 2000, the filing date of the parent application, US 09/607,745.

#### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

#### **Specification**

Insert, as the first sentence of the specification, the following.

—This application claims the benefit of priority to parent application US 09/607,745, filed June 30, 2000, which issued as US 6,750,034 on June 15, 2004.—

**Abstract**

Replace the Abstract with the following.

–Polypeptides corresponding to a novel S1 serine protease family member, termed protease D-G, and nucleic acids encoding them are described. The materials may be used, for example, in screening assays to identify protease D-G modulators and in methods for diagnosing or treating conditions associated with aberrant protease D-G activity.–

**Title**

Replace the title with: –A human serine protease D-G polypeptide–

**Claims**

Cancel Claims 1-12, 14, and 15.

Replace Claim 13 with the following.

13. A protein in substantially pure form having protease D-G proteolytic activity, wherein the protein comprises the sequence set forth by SEQ ID NO: 2.

Authorization for this examiner's amendment was given in an electronic, e-mail interview with Linda Evans on January 20, 2006.

***Allowable Subject Matter***

Claim 13 is allowed.

The following is an examiner's statement of reasons for allowance:

The elected claim, Claim 13, is limited to an isolated protein comprising the sequence set forth by SEQ ID NO: 2. The utility of the protein set forth by SEQ ID NO: 2, as a protease, is credible based on expression in heterologous host cells and analysis by an enzymatic assay using a variety of synthetic substrates (Table 1). Furthermore, as asserted by Applicants (pg 3, para 1),

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because the protease of SEQ ID NO: 2 is derived from a human host, it is less likely to induce an allergic reaction in sensitive individuals, and therefore would be useful for formulation of compositions for laundry detergents and skin care products.

The art also provides a patentable utility for the protein of SEQ ID NO: 2, based on homology to known proteins. SEQ ID NO: 2 has 99.8% homology to a human protease taught by Iwamura et al, 2000. In addition, the mouse orthologue of Iwamura's protease, as taught by Vuagniaux et al, 2002, has 79% homology to SEQ ID NO: 2. (See enclosed alignments.) Vuagniaux et al teach that their mouse protein regulates the conductance properties of the epithelial sodium channel (Figs 3, 4 & 5 and Tables I-III). The skilled artisan would believe that, more likely than not, the protein of SEQ ID NO: 2 is also able to regulate the conductance properties of the epithelial sodium channel.

Thus, the recited invention has a specific, substantial, and credible utility.

*Additional Art of Interest*

Bandman et al, 2001, US patent 6,203,979, (IDS) teaches a polypeptide, SEQ ID NO: 6 therein, having 99.8% identity with SEQ ID NO: 2 herein (see enclosed alignment).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.  
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**SHERIDAN SWOPE, Ph.D.**  
**PATENT EXAMINER**